

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,345	03/25/2002	Jan Gerrit Garssen	5034US	8607
7590 04/03/2007 Trask Britt & Rossa PO Box 2550			EXAMINER	
			SWARTZ, RODNEY P	
Salt Lake City, UT 84110			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MO	NTHS	04/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	·	Application No.	Applicant(s)			
Office Action Summary		09/913,345	GARSSEN ET AL.			
		Examiner	Art Unit			
		Rodney P. Swartz, Ph.D.	1645			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)[🛛	Responsive to communication(s) filed on <u>1Febr</u>	ruary2007.				
2a)□		action is non-final.				
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
9,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
	·					
Dispositi	on of Claims					
4)🖂	4)⊠ Claim(s) <u>1-7,11-16,20 and 21</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)🖂	Claim(s) 20 and 21 is/are allowed.					
6)⊠	6)⊠ Claim(s) <u>1-7 and 11-16</u> is/are rejected.					
7)	Claim(s) is/are objected to.		·			
8)[	8) Claim(s) are subject to restriction and/or election requirement.					
Applicati	on Papers					
	The specification is objected to by the Examiner	-				
•	<u> </u>	<u> </u>	yaminer			
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Try The bath of declaration is objected to by the Examiner. Note the attached Office Action of form 1.10-102.						
Priority u	ınder 35 U.S.C. § 119	·				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice Notice Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal Pa	te			

Application/Control Number: 09/913,345

Art Unit: 1645

## **DETAILED ACTION**

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 November 2006 has been entered.
- 2. Claims 1-7, 11-16, 20, and 21 are pending and under consideration.

## **Rejections Maintained**

3. The rejection of claims 1-5, 11-13, and 15 under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) is maintained for reasons of record.

Applicants argue that the amendment to claims 1 and 21 to recite determining with anti-PrP<sup>SC</sup> antibodies instances of increased antibody reactivity as a function of denaturation in quanidine thiocyanate or one or more chaotropic agents in the test set versus the control set should place the claims into allowance as being novel and non-obvious over the cited art.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in prior Office Actions. Claim 1 is a method for reducing false-positive test results when testing  $\geq 1$  sample for the presence/absence of an aberrant prion protein, wherein said method comprises splitting one sample into a test and control set; treating the test set with quanidine thiocyanate or  $\geq 1$  chaotropic agent; leaving the control set untreated with quanidine thiocyanate or  $\geq 1$  chaotropic agent; mixing both the test and control sets with anti-PrP<sup>SC</sup> antibodies; and determining increased antibody activity in the test set versus the control set.

Application/Control Number: 09/913,345

Art Unit: 1645

The procedures taught by Grathwohl et al do teach the claim requirements. A sample is taken (brain and spleen, page 206, section 2.2). Two sets of sample preparations are made (GdnSCN, 0-5M; SDS) from the same sample. ELISA procedures are performed and the results of the GdnScn versus SDS sets compared (sections 2.4, 3.1; Fig. 2).

4. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) is maintained for reasons of record.

Applicants argue that because independent claim 1 is nonobvious, the dependent claims 6 and 7 are nonobvious.

The examiner has considered applicants' argument, but does not find it persuasive. Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, <u>64</u>:205-216, 1997) and dependent claims 6 and 7 remain rejected for the reasoning put forth in prior Office Actions.

5. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is maintained for reasons of record.

## Conclusion

- 6. Claims 1-7 and 11-16 are rejected. Claims 20 and 21 appear to be free of the prior art.
- 7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

Art Unit: 1645

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

March 19, 2007